IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE: SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION	MDL No. 2775 Master Docket No. 1:17-md-2775 JUDGE CATHERINE C. BLAKE THIS DOCUMENT RELATES TO THE FOLLOWING CASES: *Paula and Jace Redick v. Smith & Nephew, Inc.*, No. 1:17-cv-00944 *Phyliss Mosca v. Smith & Nephew, Inc.*, No. 1:18-cv-03520

MEMORANDUM

Now pending are competing motions filed by plaintiffs Paula and Jace Redick ("Ms. Redick") and Phyliss Mosca ("Ms. Mosca") and the defendant Smith & Nephew to exclude the testimony of certain expert witnesses in advance of the first case slated for trial in this multidistrict litigation, *Paula and Jace Redick v. Smith & Nephew, Inc.*, or—should that case drop out—its backup, *Phyliss Mosca v. Smith & Nephew, Inc*. These motions require the court to decide whether certain proffered testimony concerns matters preempted from litigation, whether the experts are qualified to offer the challenged opinions, and whether the opinions are unreliable. The matter is fully briefed and oral argument was heard on April 14, 2021. For the reasons stated herein, the court will grant in part, reserve in part, and deny in part Smith & Nephew's motions to exclude Dr. Shapiro's testimony (ECF 2517, 2519), deny Ms. Redick's motion to exclude Dr. Seyler's testimony (ECF 2512), and grant in part and deny in part Ms. Mosca's motion to exclude Dr. Hungerford's testimony (ECF 2511).

LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence, which "was intended to liberalize the introduction of relevant expert evidence," *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999), provides that a qualified expert witness "may testify in the form of an opinion or otherwise if . . . [his or her] scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). The expert's testimony must be "based on sufficient facts or data" and must be "the product of reliable principles and methods." Fed. R. Evid. 702(b), (c). And the expert must "reliably appl[y] the principles and methods to the facts of the case." Fed. R. Evid. 702(d).

It is the district judge's responsibility to make an initial determination of an expert's qualifications, *see* Fed. R. Evid. 104(a), and to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 597 (1993). Relevant evidence is of course that which "helps the trier of fact to understand the evidence or determine a fact in issue." *McKiver v. Murphy-Brown, LLC*, 980 F.3d 937, 959 (4th Cir. 2020) (internal quotation marks omitted). Reliable expert testimony is "based on scientific, technical, or other specialized knowledge and not on belief or speculation" and derives any inferences "using scientific or other valid methods." *Id.* (internal quotation marks omitted). The Supreme Court has identified five factors that the court may consider in evaluating the reliability of an expert's reasoning or methodology: (1) whether the particular scientific theory has been or can be tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; (4) whether there are standards controlling the method; and (5) whether the technique has gained general acceptance in the relevant scientific community. *See Daubert*, 509 U.S. at 593–94. These factors, which "may or may not be pertinent in assessing

reliability," are not meant to be "definitive" or to constitute a "checklist." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150, 151 (1999) (internal quotation marks omitted).

"As in all questions of admissibility," the party seeking the admission of expert testimony "must come forward with evidence from which the court can determine that the proffered testimony is properly admissible"—i.e., that it is reliable and relevant. *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Yet the trial court's role as a gatekeeper is not intended to serve as a "replacement for the adversary system, and consequently, the rejection of expert testimony is the exception rather than the rule." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices and Prods. Liab. Litig.*, 892 F.3d 624, 631 (4th Cir. 2018) (internal quotation marks omitted).

ANALYSIS

This memorandum concerns motions to exclude the testimony of (1) Dr. Jeffrey Shapiro, the plaintiffs' general and specific causation expert in both cases; (2) Dr. Thorsten Seyler, Smith & Nephew's specific causation expert in Ms. Redick's case; and (3) Dr. Marc Hungerford, Smith & Nephew's specific causation expert in Ms. Mosca's case.

I. Dr. Shapiro

Invoking Federal Rules of Evidence 702 and 401–403, Smith & Nephew challenges Dr. Shapiro's opinions regarding Smith & Nephew's conduct, the causal effect on Dr. Bowling and Dr. Boucher, and medical causation as to both Ms. Redick (ECF 2517-1) and Ms. Mosca (ECF 2519-1).

A. Smith & Nephew's Conduct and Preemption

Smith & Nephew argues that Dr. Shapiro's opinions with respect to both Ms. Redick and Ms. Mosca are predicated on preempted legal theories and are also unreliable and unhelpful. In their opposition, the plaintiffs represent that Dr. Shapiro has no intention to testify about regulatory matters, and that he will follow this court's *Daubert* ruling excluding testimony relating only to preempted claims. (ECF 2590, Opp'n at 6). The plaintiffs argue that just because "a piece of evidence may be relevant to a claim the Court has ruled is preempted does not mean that same piece of evidence is somehow cloaked in irrelevance to other surviving claims." (*Id.* at 9). They submit that many of these issues are "best left to be decided by the court with the additional context sure to be present during trial," and represent that they and their experts "will only refer to [these issues] to support their surviving claims." (*Id.*). The court will address each of the challenged opinions in turn.

1. The BHR's FDA-approved labeling and instructions for use ("IFU") did not adequately warn doctors or the public of the BHR's risks. (*See* ECF 2517-3, Shapiro (Redick) Report at 11).
2. The plaintiffs would not have received the BHR if the smaller head sizes had never been placed on the market or if they had been withdrawn. (*See* ECF 2517-3, Shapiro (Redick) Report at 17; ECF 2519-3, Shapiro (Mosca) Report at 20).

This court has previously held that any claim that Smith & Nephew had a duty to change its labeling, communicate information directly to patients or the medical community, or voluntarily withdraw its product from the market is preempted. *See In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implants Prods. Liab. Litig.* (hereinafter "*In re BHR*"), 300 F. Supp. 3d 732, 737 n.5, 745 (D. Md. 2018); *see also In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig.* (hereinafter "*Daubert* Ruling"), MDL No. 2775, 2021 WL 781682, at *6, *7, *8, *9 (D. Md. Mar. 1, 2021). The plaintiffs offer no plausible theory for a surviving claim to which these statements would be relevant and they appear to concede that Dr.

Shapiro should not and will not discuss any claims, such as these, which already have been excluded from this litigation. (*See* ECF 2590 at 6). For this reason, these opinions will be excluded.[1]

3. Surgeons would have wanted to know current risk information from Dear Doctor letters, educational conferences, and training. (ECF 2517-3, Shapiro (Redick) Report at 12; ECF 2519-3, Shapiro (Mosca) Report at 14).

Smith & Nephew contends that Dr. Shapiro's report states that it should have provided additional information through Dear Doctor letters, educational conferences, and more. If Dr. Shapiro were to offer such an opinion, it would likely be preempted. *See Daubert* Ruling at *8. But a careful reading of the cited portion of Dr. Shapiro's report reveals that it does not contend Smith & Nephew had a duty to send additional communications, but rather that implanting surgeons would have wanted to know this information. (*See* ECF 2517-3, Shapiro (Redick) Report at 12 ("Surgeons generally, and Dr. Bowling in particular, are receptive to receiving risk information from various educational sources. Dr. Bowling would have wanted to know current risk information from whatever source possible, including Dear Doctor Letters, educational conferences, training, and the like."). Dr. Shapiro's testimony is potentially relevant to causation, as surgeons must be receptive to revised data for such data to have any effect on their clinical decisions. But while it may be appropriate for Dr. Shapiro to testify as to what a reasonable surgeon would want to know, Dr. Shapiro is not qualified to testify as an expert as to what Dr. Bowling himself would have wanted to know. *See* Fed. R. Evid. 702(a) (expert testimony must be based on the expert's scientific, technical, or other specialized knowledge); *see also In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1069 (D. Minn. 2007) (excluding physician-expert's personal

[1] Smith & Nephew also contends that Dr. Shapiro is not qualified to offer testimony on regulatory matters such as these. The court need not and does not reach this issue.

opinions about what other physicians knew or would have done with different information). Dr. Bowling of course may testify as to what he would have wanted to know. Accordingly, the court will reserve ruling on whether Dr. Shapiro may testify that surgeons generally would have wanted certain additional information until, in the context of trial, it is better able to make a relevance determination; but the court will exclude any testimony offered by Dr. Shapiro opining as to what Dr. Bowling or Dr. Boucher would or would not have done with additional information.

4. The metal-on-plastic design is the gold standard and metal-on-metal is a bad idea. (ECF 2517-3, Shapiro (Redick) Report at 13; ECF 2519-3, Shapiro (Mosca) Report at 16).

It appears this testimony may be relevant only to a preempted design defect claim. Though a misrepresentation claim is not categorically preempted, the plaintiffs in this case appear to rely on Smith & Nephew's alleged misrepresentations relating to the superiority of the BHR over other metal-on-metal devices, and not over metal-on-plastic devices. It is not entirely clear from the briefing, however, whether Dr. Shapiro's opinion regarding the superiority of metal-on-plastic will be offered at trial in support of a non-preempted claim; nor is it clear what the theory of relevance would be. Given this uncertainty, the court will defer a final ruling on this testimony until its relevance is clarified in the context of trial.

5. Smith & Nephew's surgeon training was inadequate because surgeons were taught "there were no contraindications for women (outside of childbearing)," because the 500 to 1,000 surgery learning curve was not disclosed during training in 2006, and because the training omitted information challenging the McMinn data. (ECF 2517-3, Shapiro (Redick) Report at 7, 10, 12–13; *see also* ECF 2519-3, Shapiro (Mosca) Report at 15).

Smith & Nephew contends that these opinions impermissibly challenge FDA-approved labeling insofar as Dr. Shapiro appears to be opining that its training should have included information challenging data which was (1) submitted as part of the PMA application, (2) reviewed by the FDA, and (3) included in the BHR label. (*See* ECF 2517-1 at 15). It is not entirely accurate

to say, as Smith & Nephew seems to suggest, that this court has excluded absolutely any testimony about its surgeon training program: rather, the court held that the plaintiffs had not identified a federal requirement which imposed on Smith & Nephew a duty to modify its surgeon training program and that without such a requirement any testimony suggesting it had a duty to do so would be excluded. *See Daubert* Ruling at *8. But the court also held that any claims challenging a warranty above and beyond any guarantee approved by the FDA were not preempted. *See id.* at *6. In reaching that conclusion, this court relied upon *Wildman v. Medtronic, Inc.*, 874 F.3d 862 (5th Cir. 2017), which itself relied on *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919 (5th Cir. 2006).

In *Gomez*, the Fifth Circuit Court of Appeals held that a breach of warranty claim was preempted because the warranty, which was part of the device's IFU, was reviewed and approved by the FDA. 442 F.3d at 932. The Court rejected Gomez's reliance on a "later-acquired knowledge theory" in which she contended that the manufacturer's knowledge of risks acquired after FDA approval obligated the manufacturer to provide updated warnings for patients and physicians. *Id.* at 931. That argument, the court held, "fails to overcome preemption" since device manufacturers "have ongoing obligations to report experience with the device to the FDA, and the FDA has plenary authority to amend the regulations and requirements it imposed relating to the device[.]" *Id.* At the same time, though, "federal law requires that representations about medical devices be truthful[,]" so when an express warranty claim rests on representations that go above and beyond what the FDA has blessed, the claim may not be preempted. *Wildman*, 874 F.3d at 868.

Here, Smith & Nephew asserts—without citing to any exhibits—that the representations about contraindications in women, the learning curve, and the McMinn data made during the surgeon training were blessed by the FDA. (*See* ECF 2517-1 at 13). The plaintiffs do not address

whether the FDA blessed these representations; rather, they contend in general terms that Dr. Shapiro's opinions are admissible to the extent they do not exclusively support preempted claims. Because it is not clear whether the testimony goes only to a preempted claim (e.g., a duty to modify the training program) or possibly to a non-preempted claim (e.g., negligent misrepresentation or a breach of express warranty), the court reserves ruling on whether the challenged statements would be admissible at trial.

Smith & Nephew next contends that these statements about surgeon training are unreliable because Dr. Shapiro does not suggest the allegedly withheld information was available when Dr. Bowling was trained in 2006 and because Dr. Shapiro has never attended a BHR training or reviewed the materials provided in such a training. (*See* ECF 2517-1 at 13–14). Smith & Nephew points to Dr. Shapiro's deposition, in which he concedes that the learning curve did not play a part in Dr. Bowling's implant for Ms. Redick, as evidence of the unreliability of his opinion. (*See* ECF 2517-9, Shapiro Dep. at 231–32). This concession by Dr. Shapiro does not undermine the reliability of his opinion that Smith & Nephew failed to disclose certain information to Dr. Bowling, but—at least with respect to the learning curve—it does raise a question of relevance, as Dr. Shapiro appears to concede that Dr. Bowling's performance was not hindered by the lack of this knowledge. Smith & Nephew may renew this objection on relevance grounds should Dr. Shapiro attempt to offer testimony about the learning curve at Ms. Redick's trial. As for the rest of Smith & Nephew's arguments, they are based on the uncertain assumption that Dr. Shapiro is challenging the adequacy of the training (which is preempted) rather than the truthfulness of extra-labeling statements made during and after the training (which may not be). The court will therefore reserve ruling on this issue until the relevance of this testimony is clarified in the context of trial.

6. Smith & Nephew had an ethical obligation to provide additional information to physicians. (ECF 2517-9, Shapiro (Redick) Dep. at 58, 140–43).

The plaintiffs represent that this statement, elicited by Smith & Nephew's counsel during Dr. Shapiro's deposition, will not be introduced at trial. (*See* ECF 2590 at 8; *see also* ECF 2517-9, Shapiro Dep. at 58 ("[T]hat's a legal question about what their obligations are, so I think there are other people that are going to speak to that issue."). Any extralegal obligations which an expert may wish to assign to Smith & Nephew are preempted insofar as they impose obligations which add to or are different from federal requirements. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008). Given the plaintiffs' concession, the fact that this opinion does not appear in Dr. Shapiro's reports, and the likelihood that such testimony would be irrelevant to any remaining claims, the court will exclude this testimony.[2]

B. Opinions about Dr. Bowling and Dr. Boucher

Next, Smith & Nephew argues that Dr. Shapiro's opinions about the effect additional information would have had on both Ms. Redick's and Ms. Mosca's implanting surgeons are inadmissible because they are predicated on preempted theories of liability, are speculative, and are contradicted by each surgeon's own testimony. In particular, Dr. Shapiro's reports state:

1. "Any reasonably knowledgeable orthopedic surgeon generally, and Dr. Bowling in particular, would not have implanted Ms. Redick with the BHR if [Smith & Nephew] had provided them with information about (a) the failure rates of the BHR, and specifically information about head sizes and the failure rate in women; and (b) the steep learning curve to achieve the advertised clinical results." (ECF 2517-3, Shapiro (Redick) Report at 1–2; *see also* ECF 2519-3, Shapiro (Mosca) Report at 2).
2. Smith & Nephew "had vital safety information which a reasonably prudent orthopedic surgeon in general, and Ms. Redick's orthopedic Surgeon, Dr. Jack Bowling, in particular, would have benefitted from in making a determination about patient selection for the BHR device." (ECF 2517-3, Shapiro (Redick) Report at 1; *see also*

[2] The court has not addressed every piece of deposition testimony cited by Smith & Nephew, but rather has focused on the testimony which clearly has a basis in Dr. Shapiro's reports and which presents issues not squarely addressed by the court's prior rulings.

ECF 2519-3, Shapiro (Mosca) Report at 2).

With respect to the first statement, Smith & Nephew contends that, since the court has already held that the plaintiffs' failure to warn claims may proceed only on the basis of an alleged failure to report information to the FDA, Dr. Shapiro may not testify that the surgeons would not have implanted Ms. Redick or Ms. Mosca with the BHR if they had been provided additional information about the BHR's failure rates and learning curve. And, they argue, because the plaintiffs have disavowed any attempt to litigate what the FDA might or might not have done if presented with different or additional information, the plaintiffs are left with no viable theory as to how this information might have reached the surgeons in time to prevent the plaintiffs' injuries.

The plaintiffs counter that Dr. Shapiro's testimony is relevant to their surviving claims "because of Smith & Nephew's statements outside the labeling for the BHR, and its statements during surgeon training programs." (ECF 2590 at 11). They cite, for example, Dr. Shapiro's statement that Dr. Bowling was told during training that there would be no contraindications for women and no differentiation between male and female patients; they note that Dr. Bowling did not have access to the "secret reports Smith & Nephew had containing ad hoc data showing soaring revision rates for women and smaller head sizes, or to the analyses of adverse events and complaints"; and they state that Dr. Bowling was told the BHR was superior to other metal-on-metal hip systems in marketing materials and letters from Smith & Nephew. (*Id.*).

As the plaintiffs' opposition tacitly concedes, Smith & Nephew had no duty to disclose this information directly to the plaintiffs or to their surgeons. (*See* ECF 2590 at 11); *see also Daubert* Ruling at *8. And the plaintiffs have disavowed any arguments concerning discretionary actions the FDA may or may not have taken had Smith & Nephew made a required disclosure to the FDA. *See Daubert* Ruling at *13. As a result, to succeed on a failure to warn claim, the plaintiffs must

show that had certain information been disclosed to the FDA, the FDA would have necessarily made that information public in, for example, the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database. *See Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 770 & n.5, 776 (5th Cir. 2011). Such a showing has not been made, *see Cline v. Advanced Neuromodulation Sys.*, Inc., 17 F. Supp. 3d 1275, 1286 (N.D. Ga. 2014), and Dr. Shapiro's opinion is therefore not relevant to any surviving failure to warn claim and may not be offered for that purpose. Further, insofar as it may be relevant to a misrepresentation or breach of express warranty claim, the opinion is not the product of reliable methods, since Dr. Shapiro's conclusion regarding Dr. Bowling's hypothetical actions was drawn from reading Dr. Bowling's straightforward testimony to that effect and cannot have been formed using any scientific or technical expertise. (*See* ECF 2517-9, Shapiro (Redick) Dep. at 144–45 ("I don't think any doctor including Dr. Bowling in this case who said he would have looked forward to [additional] information, he would have accepted the information, he would have wanted the information. He states that in his deposition.")).[3]

With respect to the second statement, Smith & Nephew argues that this court has held that the plaintiffs' experts may not speculate as to actions the FDA may or may not have taken, and that this reasoning applies with equal force to speculation about actions Dr. Bowling may or may not have taken with additional or different information. Smith & Nephew cites Dr. Shapiro's admission, given during his deposition for the Sedgwick case, (*see* ECF 2517-12, Shapiro (Sedgwick) Dep. at 133), that his ability to predict what anyone would do with certain information was a product of common sense, and argues that this cannot qualify as scientific, technical, or other

[3] Further, the opinion may not survive a Rule 403 challenge as it appears needlessly cumulative given that Dr. Bowling will testify as to whether he would have proceeded with an implant had he known this information.

specialized knowledge under Federal Rule of Evidence 702.[4]

The plaintiffs counter that Dr. Shapiro is not attempting to predict the exact steps the implanting surgeons would have taken if they had received certain information. They also argue that Dr. Shapiro's extensive experience making similar decisions with patients over the past four decades is a stronger foundation to render such an opinion than just a lay person's common sense.

Dr. Shapiro's opinion does not state what Dr. Bowling would or would not have done with certain information. Rather, it states that Dr. Bowling would have benefitted from the additional information when making a determination about patient selection for the BHR device. Despite one stray statement, made in a deposition for a separate case, that Dr. Shapiro's opinion is based on common sense, the court finds it plausible that his extensive experience informs his judgment that the doctors would have benefitted from the particular information at issue here. A juror may not know whether a doctor would find certain categories of information pertinent or helpful in making the clinical decision whether to select a certain product for a patient's hip implant, given the technical nature of some of the information at issue. The court notes, however, that this testimony may not survive a 403 challenge, as Dr. Bowling is in a far better position to state what information would have been beneficial to him—or, more relevant yet, what information would have changed his clinical decision to use the BHR.

[4] Smith & Nephew cites *Gary v. Prof'l Div., Alberto-Culver Co.*, 884 F.2d 1388 (4th Cir. 1989) (per curiam) (unpublished) for the proposition that expert testimony based on common sense must be excluded. In *Scott v. Sears, Roebuck & Co.*, 789 F.2d 1052 (4th Cir. 1986), the court noted that, under Rule 403 rather than under Rule 702, "[t]rouble is encountered only when the evaluation of the commonplace by an expert witness might supplant a jury's independent exercise of common sense." *Id.* at 1055; *see also Koenig v. Johnson*, No. 2:18-cv-3599-DCN, 2020 WL 2308305, at *5–6 (D.S.C. May 8, 2020). The court also noted that Rule 702 makes inadmissible expert testimony "as to a matter which obviously is within the common knowledge of the jurors because such knowledge, almost by definition, can be of no assistance. At the same time, admission of such testimony, though technical error, will almost invariably be harmless." *Scott*, 789 F.2d at 1055.

It is a separate question, though, whether Dr. Shapiro may rely on information unavailable to Smith & Nephew at the time of Ms. Redick's implant surgery to offer these opinions. Specifically, Smith & Nephew challenges Dr. Shapiro's reliance on a chart of revision data from March 2012, a video released by Dr. McMinn in 2015, and ad hoc reports from the Australian registry which Smith & Nephew may not have been authorized to disclose. (*See* ECF 2517-3, Shapiro (Redick) Report at 8, 13; ECF 2517-9, Shapiro (Redick) Dep. at 73, 188–92).

The chart is an analysis of revision rates from a March 2012 ad hoc report (Report 858), which Dr. Shapiro states "confirms the conclusion of other reports, such as Ad Hoc Report 581 . . . and adverse event data from the NJREW received and analyzed on April 15, 2011 and January 31, 2012, as well as other analyses of adverse events and complaints[.]" (ECF 2517-3, Shapiro (Redick) Report at 8). Thus, even assuming that Dr. Shapiro's reliance on the 2015 video is not a reliable method of determining whether information was withheld from Dr. Bowling, Dr. Shapiro's conclusion does not rest purely on data derived only after Ms. Redick's March 20, 2012, surgery. It is therefore not unreliable on the basis which Smith & Nephew suggests.[5]

C. Medical Causation

Finally, Smith & Nephew argues that Dr. Shapiro's medical causation analysis is unreliable because he fails to account for other potential causes supported in the medical records, and that testimony concerning his examination of Ms. Redick and Ms. Mosca should be excluded as

[5] And as a factual matter it is not so clear, as Smith & Nephew contends, that it was unable to share the ad hoc reports. Dr. Shapiro concedes that he believed the company was not supposed to disseminate the information without the permission of the registry. (*See* ECF 2517-9, Shapiro Dep. at 73, 139–40). But Smith & Nephew does not cite any exhibits showing whether Smith & Nephew requested permission to share the specific data Dr. Shapiro cites in his report; nor does Smith & Nephew cite to a regulatory expert on the matter. And at least in the context of a misrepresentation claim, one need not disclose the full ad hoc report to avoid making a misrepresentation; rather, Smith & Nephew could have altered the affirmative representations it was making to avoid making the omission of the ad hoc report materially misleading.

untimely and for violating state medical licensure requirements. The court will first address the motion as it pertains to Ms. Redick and then as it pertains to Ms. Mosca.

1. Ms. Redick

A differential diagnosis is "a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Westberry*, 178 F.3d at 262. This technique typically entails a physical examination and review of clinical tests and medical histories and is accomplished by "determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching the one that cannot be ruled out or determining which of those that cannot be excluded is the most likely." *Id.* (citing *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 807 (3d Cir. 1997)).

Yet "simply calling an analysis a differential diagnosis doesn't make it so." *In re Lipitor*, 892 F.3d at 643. While a reliable differential diagnosis "need not rule out all possible alternative causes," it still "must at least consider other factors that could have been the sole cause of the plaintiff's injury." *Id.* at 644 (internal quotation marks omitted); *see also Westberry*, 178 F.3d at 265 ("A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation."); *see also In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 764–65 (3d Cir. 1994) (similar).

After a plaintiff's specific causation expert offers a differential diagnosis to support a medical causation opinion, a defendant "need not [also] conduct a differential diagnosis to identify the specific cause of an injury because" the defendant does "not bear the burden of proving causation." *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2017 WL 132165, at *2 (S.D.W. Va. Jan. 12, 2017) (citing 3 David Faigmen et al., Modern Sci. Evidence § 21:6 (2015–2016 ed.)); *see also Goodrich v. John Crane, Inc.*, No. 4:17cv9, 2018 WL 4677773,

at *9 (E.D. Va. Sept. 28, 2018) (distinguishing plaintiffs' burden of proof from defendant's burden to establish the reliability and relevance of proposed expert testimony). Rather, a defense specific causation witness "is tasked with giving testimony that affects the weight and potentially the admissibility of the plaintiff's specific causation expert." *In re Ethicon*, 2017 WL 132165, at *2. "So long as the defense specific causation expert's opinion is a product of his specialized knowledge or training and is reliably grounded, it should be admissible to rebut the plaintiff's specific causation expert." *Id.* If the plaintiff's expert can offer "*no* explanation for why she has concluded an alternative cause offered by the opposing party was not the sole cause," then the differential diagnosis is unreliable. *Westberry*, 178 F.3d at 265 (internal quotation marks and alterations omitted) (emphasis in original). Otherwise, the alternative causes suggested by a defense expert "affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony[.]" *Id.* (internal quotation marks omitted); *see also Kannankeril*, 128 F.3d at 808 (to attack a differential diagnosis the defendant may point to a plausible cause of the plaintiff's illness other than the defendant's actions and it then becomes necessary for the plaintiff's expert to offer an explanation as to why his or her conclusion remains reliable).

In this case, Dr. Shapiro opines that the BHR implant "caused Ms. Redick's pain, limited range of motion and antalgic gait; . . . synovitis; reduced motion; and elevated ions." (ECF 2517-3, Shapiro (Redick) Report at 16). In turn, he contends, those "symptoms and the rising metal ion levels caused Ms. Redick to require revision surgery." (*Id.*). Smith & Nephew argues that Dr. Shapiro failed to exclude three alternative causes—a potential femoral stress fracture, smoking, and post-operation falls—and failed to explain that Ms. Redick's chromium levels were decreasing over time.

First, as to the femoral stress fracture and Ms. Redick's falls, there is no indication that Dr.

Shapiro completely disregarded these as potential sources of Ms. Redick's pain. Smith & Nephew's expert Dr. Seyler mentions, in the context of explaining all the possible causes that should be part of Ms. Redick's differential diagnosis, that "there is a lot going on in this case," including the possibility that "it looks like there may be a hairline fracture" on the CT scan even though "[i]t's not the most accurate way to diagnose" a fracture. (ECF 2512-6, Seyler Dep. at 102–03). Dr. Seyler also concedes that there is no indication in the medical records that Dr. Bowling or any other physician actually diagnosed a femoral neck fracture. (*See id.* at 104). For his part, Dr. Shapiro explained to counsel for Smith & Nephew when questioned about this and other possible alternative causes:

> [T]here is a potential for a fall impact . . . [to] create a fracture. However, there's no document to the effect that that actually happened . . . so it falls into the category anything can happen. Let's talk about the specifics of the case. She had multiple x-rays showing there was no disturbance of the implant, there were no fractures. So I don't think we have any documentation that a fall caused her failure. And . . . a fall . . . by itself does not cause metallosis, and she had metallosis. Look at her blood tests.

(ECF 2517-9, Shapiro (Redick) Dep. 137). Dr. Shapiro was therefore confronted with and considered the proposed alternative causes, such as a femoral stress fracture resulting from a fall, that he explains are less likely to have necessitated Ms. Redick's revision surgery. This is distinct from *In re Lipitor*, where the expert ruled out several risk factors for which the risk greatly exceeded the risk posed by the defendant's product and nevertheless concluded that the defendant's product was a substantial contributing factor in causing the plaintiff's injuries. *See* 892 F.3d at 644. The court does not find Dr. Shapiro's differential diagnosis unreliable on this basis, as doctors need not rule out every conceivable cause for their differential diagnosis to be admissible. *See Westberry*, 178 F.3d at 265.

As for smoking, Dr. Shapiro's report does not consider that factor in its differential

diagnosis. Dr. Shapiro readily admitted in his deposition that "we know smoking is poison and that it can impact . . . healing . . . [and] the ability to fix the bone to the implant." (ECF 2517-9, Shapiro (Redick) Dep. at 274). But he goes on to state that in Ms. Redick's case, the bone was "cemented, so we're not worrying about the ingrowth of bone," and in any event, "smoking does not cause you to have more metal-on-metal debris from a hip replacement," so he did not "think smoking really has anything to do with" Ms. Redick's case. (*Id.* at 274, 275). Dr. Shapiro may not have included smoking in his differential diagnosis, but neither does Dr. Seyler state that smoking was the likely cause, or even a potential cause, of Ms. Redick's revision surgery.[6] This case is therefore not like *Cooper v. Smith & Nephew, Inc.*, where an expert physician disregarded the medical literature, the plaintiff's medical records, and the opinion of the plaintiff's treating physician that smoking was the main cause of the plaintiff's injuries, all without explaining how he ruled out smoking as a potential cause. 259 F.3d 194, 202–03 (4th Cir. 2001). Dr. Shapiro's conclusion is not un-reasoned or unreliable for failing to explicitly rule out smoking.

And as to Dr. Shapiro's alleged ignorance of Ms. Redick's declining chromium and cobalt levels, which apparently dropped from 13.7 (chromium) and 11.4 (cobalt) in 2016 to 6.0 (chromium) and 6.6 (cobalt) by the time of revision, he admits in his deposition that he "made a

[6] Indeed, as explained in Section II.C, *infra*, Dr. Seyler does not offer his own differential diagnosis, and when he discussed the factors that should be present in a differential diagnosis during his deposition, he did not mention smoking. Rather, Dr. Seyler's report appears to discuss smoking insofar as it "increases the risk of sustaining a fracture"—which is offered as one of his potential alternative causes. (ECF 2512-7, Seyler Report at 10). But smoking does not appear to be offered as a potential alternative cause in and of itself. *See Huskey v. Ethicon*, 29 F. Supp. 3d 691, 727 (S.D.W. Va. 2014) (defendant may point to a "plausible cause" of the plaintiff's illness other than the defendant's actions to attack a differential diagnosis); *Kannankeril*, 128 F.3d at 808 (same); *see also Rhyne v. U.S. Steel Corp.*, 474 F. Supp. 3d 733, 753, 754 (W.D.N.C. 2020) (holding that where defense experts and defense counsel conceded potential alternative cause was insufficient to cause the alleged injury, the alternative cause was not "plausible" such that a plaintiff's expert must rule it out to establish the reliability of a differential diagnosis).

mistake" and the levels were actually decreasing—but, he stated, "it's still abnormal" insofar as any numbers over three are concerning. (ECF 2590-4, Shapiro Dep. at 262). As Dr. Shapiro explains, Ms. Redick's levels were nevertheless abnormal and she was symptomatic and experiencing pain; his theory is thus that Ms. Redick's pain caused her to reduce her activity level, which in turn caused the BHR to wear at a slower rate, leading to the lower levels. (*Id.* at 264–66). The court therefore will not exclude Dr. Shapiro's testimony as unreliable because of this oversight. *See Westberry*, 178 F.3d at 265.

Finally, Smith & Nephew also argues that evidence of Dr. Shapiro's examination of Ms. Redick is inadmissible because it was not included in his report and because it violated North Carolina's medical licensing requirements. Dr. Shapiro submitted his report on Ms. Redick in December of 2020, and conducted an examination of her only after the fact. He initially did not request to examine Ms. Redick, but after learning that Dr. Seyler had conducted an examination, he sought to do the same "to make sure that" Dr. Seyler's observations were "reasonably close" to his own. (ECF 2517-9, Shapiro (Redick) Dep. at 39). Under Fed. R. Civ. P 26(a)(2)(B)(i), an expert report is to contain a complete statement of all opinions the witness will express and the basis and reasons for them. But Smith & Nephew had the opportunity to question Dr. Shapiro at his deposition about the examination, (*see* ECF 2517-9, Shapiro (Redick) Dep. at 38), and there is no indication that the results of the examination significantly affected the opinions expressed in his report. Exclusion of his testimony on this point is not warranted.

As for the purported violations of North Carolina medical licensing requirements, Smith & Nephew points to licensure provisions requiring any licensee regularly practicing telemedicine with patients located in North Carolina to be licensed in North Carolina, and requiring out of state providers to apply for an emergency license in North Carolina before delivering services in the

state. In support of this position, Smith & Nephew cites *Perfect 10, Inc. v. Giganews, Inc.*, NO. CV 11-07098-AB (SHx), 2014 WL 10894452, at *6 (C.D. Cal. Oct. 31, 2014), for the proposition that testimony contrary to public policy may be excluded under a court's inherent powers. But there is a vast difference between an expert conducting a brief telehealth examination in the midst of a global pandemic and the facts at issue in *Perfect 10*, where the expert physician had "an overwhelming conflict of interest by way of his direct financial stake in the outcome of the litigation" and where the court was skeptical that the physician "qualifies as an expert for the purposes of [the] litigation at all." *Id.* at *1, *6. Further, Dr. Shapiro was not examining Ms. Redick for purposes of treatment. The court will therefore decline to exercise its inherent powers to exclude Dr. Shapiro's testimony on this basis.

2. Ms. Mosca

Next, Smith & Nephew also challenges Dr. Shapiro's causation opinions with respect to Ms. Mosca. It first challenges his causation opinion insofar as it relies on a pathology expert's interpretation of slides from Ms. Mosca's revision, concluding that Ms. Mosca experienced an adverse tissue reaction even though the pathology report does not contain the words "ALVAL" (aseptic, lymphocyte-dominated vasculitis-associated lesion) or "metallosis." Because Dr. Shapiro is not a pathologist, Smith & Nephew contends he is unqualified to offer this opinion. In his deposition, Dr. Shapiro admits that an "orthopedic type pathologist" would be better qualified to read such a slide, but he also states that orthopedists such as himself "have some knowledge of pathology through our experience in treating patients[.]" (ECF 2519-9, Shapiro (Mosca) Dep. at 176). As this court previously held, a court must consider a proposed expert's "full range of experience and training"—not just his "professional qualifications"—in deciding whether the expert has "sufficient specialized knowledge" to assist the jurors in deciding issues in the case. *See*

Daubert Ruling at *10 (quoting *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012)). Just because someone else might be better qualified to interpret the slides does not mean that Dr. Shapiro is unqualified to do so in the context of developing his opinion on causation.

Smith & Nephew also argues that Dr. Shapiro's report fails to account for other factors—such as referred back pain—that could have been the sole cause of Ms. Mosca's injury. Dr. Shapiro acknowledged Ms. Mosca's referred back pain in the context of explaining why Ms. Mosca may have hesitated to do the revision surgery at a point when revision might not have alleviated all of her pain, which at that time she described as mild. (*See* ECF 2519-9, Shapiro (Mosca) Dep. at 160–61). Smith & Nephew appears to take this reference to back pain out of context to introduce a new alternative cause that Dr. Shapiro must then explain away; there is no indication in any testimony before the court that Ms. Mosca's referred back pain was the cause of her revision surgery.

Next, Smith & Nephew also argues that Dr. Shapiro is not qualified to offer opinions on whether Ms. Mosca's medical bills are fair and reasonable. (*See* ECF 2519-3, Shapiro (Mosca) Rep. at 20 ("I reviewed Ms. Mosca's billing records for the treatment she underwent for her failed hip resurfacing procedure. In my opinion, the billing records are fair and reasonable, and the procedure was medically necessary."). The plaintiffs do not appear to contest this issue. Dr. Shapiro does not routinely look at medical bills and gave Ms. Mosca's bills only a cursory review. There is thus "no basis for the Court to conclude he has 'specialized knowledge' regarding medical billing practices that will help the fact-finder[.]" *Morris v. Biomet, Inc.*, 491 F. Supp. 3d 87, 101 (D. Md. 2020) (physician-expert admitted he merely looked at medical bills to determine whether they were reasonable, and stated he does not routinely review patient medical bills).

Finally, Smith & Nephew argues that evidence from Dr. Shapiro's examination should be excluded because it was conducted in violation of Maryland medical licensing laws. For the same

reasons discussed above with respect to Dr. Shapiro's examination of Ms. Redick, the court likewise declines to exclude Dr. Shapiro's testimony on this basis.

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In sum, the court will exclude Dr. Shapiro's opinions that challenge FDA-approved labeling, that state Smith & Nephew had any moral or ethical duties, or that state Smith & Nephew had a duty to warn physicians or patients directly, to modify its surgeon training program, or to withdraw its products from the market. Such opinions are relevant only to preempted claims. The court will also exclude as unreliable Dr. Shapiro's opinions about what Dr. Bowling or Dr. Boucher would have done with different information, as well as Dr. Shapiro's opinion on the reasonableness of Ms. Mosca's medical bills; such testimony is not the reliable product of Dr. Shapiro's expertise. The court reserves ruling on whether Dr. Shapiro may testify about whether surgeons generally would have benefitted from the disclosure of certain information and whether certain statements made during surgeon training go to preempted claims or surviving claims. The balance of the challenged testimony is not inadmissible on any of the grounds asserted by Smith & Nephew.

II. Dr. Seyler

Ms. Redick seeks to exclude much, if not all, of Dr. Seyler's testimony. In particular, she argues that he is not qualified to offer opinions either on regulatory compliance or the likelihood Ms. Redick would have received the BHR had Smith & Nephew not made certain misrepresentations; that he lacks the knowledge necessary to opine on the adequacy of Smith & Nephew's communications to Ms. Redick's implanting surgeon, Dr. Bowling; and that there is no factual basis for his opinion that either a history of smoking or a bone fracture, rather than the BHR, may have necessitated Ms. Redick's revision surgery. The court addresses each in turn.

A. Regulatory Compliance

Ms. Redick contends that Dr. Seyler admits he is not a regulatory expert but nevertheless opines on "the adequacy of safety warnings communicated to Dr. Bowling" and on "the information and representations that Dr. Bowling was aware of when making his decision to use the BHR system[.]" (ECF 2512-1, Mot. to Exclude at 4). Smith & Nephew counters that these are strawmen arguments, as Dr. Seyler does not actually opine on regulatory matters or the adequacy of its warnings.

The testimony at issue includes the following passages:

> It is my opinion that Dr. Bowling was adequately informed of the risks and complications associated with the use of a hip resurfacing device through information available to him. As per his deposition he attends scientific meetings and stays current with research in the field of adult reconstruction. Dr. Bowling advised Ms. Redick specifically about the advantages and potential complications of hip resurfacing during a pre-operative visit on October 12, 2011. He told her about the risk of metallosis and elevated metal ions. He mentioned that hip resurfacing would be a good option because it would allow her to return to her prior activities, which is consistent with the literature. He also told her about the possible development of inflammation, pain, and osteolysis. . . . I disagree with Dr. Shapiro's opinion that Dr. Bowling was not adequately advised of the possible risks of the BHR. Dr. Bowling kept up with the literature and attended scientific meetings. His notes reflect a lengthy discussion with Mrs. Redick about the possible risks of the BHR. He told Mrs. Redick that she may need a revision to the BHR in the future. . . . As shown by the registry and other data . . . the BHR was a good choice for Mrs. Redick in 2012 . . . . I disagree with Dr. Shapiro that Mrs. Redick would have had a better outcome with a different device.

(ECF 2512-7, Seyler Report at 14, 16, 17).

The challenged testimony does not state an opinion about regulatory compliance. Dr. Seyler disclaimed any attempt to comment on what and when certain information should have been communicated to the FDA or to surgeons. (*See id.* at 13). Instead, Dr. Seyler appears to be discussing, from a surgeon's perspective and after reviewing the notes from Ms. Redick's medical treatment, whether Dr. Bowling was aware of the general risks that might result from the hip

implant surgery. Dr. Seyler is qualified to interpret medical records for the purpose of opining on whether medical risks were disclosed, so long as he does not stray into the matter of Smith & Nephew's regulatory compliance. *Cf. Daubert* Ruling at *12 (concluding that Dr. Shapiro was not qualified to opine on Smith & Nephew's compliance with FDA regulations but was qualified to opine on the adequacy of its training program from the perspective of an implanting surgeon).[7]

Nor is the testimony unduly hypothetical. It does not speculate whether Ms. Redick would have proceeded with her surgery had she known all the risks; rather, Dr. Seyler disagrees with the opinion offered by Dr. Shapiro that Ms. Redick would have done better with a different device—an opinion that is hypothetical only to the extent that Dr. Shapiro's is.[8] Should Dr. Seyler actually seek to opine on regulatory matters outside of his area of expertise or to speculate on what Ms. Redick might have done under different circumstances, Ms. Redick may renew her objections. *See In re DePuy Orthopaedics, Inc. Pinaccle Hip. Implant Prods. Liab. Litig.*, No. 3:11-MD-2244-K, 2014 WL 3557345, at *8 (N.D. Tex. July 18, 2014) (admission of speculative testimony implicates a court's discretion over the presentation of evidence and should be taken up at trial); *see also Daubert* Ruling at *13.

B. Adequacy of Communications

Ms. Redick additionally argues that Dr. Seyler may not testify that Dr. Bowling was "adequately advised of the possible risks of the BHR" as that opinion is "contrary to the evidence and therefore not reliable." (ECF 2512-1 at 8).

[7] The court notes also that Dr. Seyler's opinion concerns whether certain categories of risk were disclosed, while the plaintiffs emphasize that Smith & Nephew failed to disclose the magnitude of those risks. This discrepancy goes to the weight of Dr. Seyler's opinion, not its admissibility.

[8] Ms. Redick notes that Dr. Bowling testified he would have shared additional information concerning the performance and risks of the BHR had he known it, and Ms. Redick has testified that she would not have gotten the BHR had the magnitude of risk been shared with her. But Dr. Seyler ultimately does not contest any of that information.

She cites several cases for the proposition that an expert may not disregard without good cause facts which are unfavorable to the expert's opinion. *See Cooper v. Meritor, Inc.*, No. 4:16-CV-52-DMB-JMV, 2019 WL 545187, at *8 (N.D. Miss. Feb. 11, 2019); *Nunez v. BNSF Ry. Co.*, No. 09-4037, 2012 WL 2874059, at *8 (C.D. Ill. July 13, 2012); *Ranes v. Adams Laboratories, Inc.*, 778 N.W.2d 677, 696–97 (Iowa 2010). *Cooper* does not directly support this position and appears to have been cited in error.[9] *Nunez* dealt with an expert who opined that a locomotive horn never sounded by discounting as unreliable the uncontradicted testimony of several witnesses such that the court found his opinion was "like saying that if a tree falls in the forest but there is no video recording of it, the tree never fell even if witnesses observed it." 2012 WL 2874059, at *6. And *Ranes* dealt with a physician-expert who offered a differential diagnosis without adhering to the accepted method: he did not "consider the variety of diseases that tend to mimic the [plaintiff's] symptoms," he "dismissed all neurological tests performed over the course of three years," and he instead relied "solely on [the plaintiff's] degenerative symptoms" to reach a diagnosis. 778 N.W.2d at 696–97. On those facts, the court held that expert analysis that discusses "only the evidence the expert believes will advance the [party's] position" and "ignores a large amount of information that calls the expert's theory into question" cannot be considered reliable. *Id.* at 697.

These cases are all distinguishable. In this case, Dr. Seyler is not—as Ms. Redick contends—simply ignoring the contention that Dr. Bowling lacked access to the ad hoc Australian registry data. Nor does it appear that Dr. Seyler is inexplicably discounting that lack of information. Dr. Seyler, after cataloguing the various risks Dr. Bowling communicated to Ms. Redick, concludes that he "disagree[s] with Dr. Shapiro's opinion that Dr. Bowling was not adequately

[9] Ms. Redick may have intended to cite *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001) (utter failure of differential diagnosis to consider other potential causes of illness may justify exclusion).

advised of the possible risks of the BHR." (ECF 2512-7, Seyler Report at 16). Thus, his opinion that Dr. Bowling was adequately advised of the possible risks of the BHR stems from his analysis of Dr. Bowling's informed consent. It may not be consistent with Ms. Redick's theory that Dr. Bowling was not advised of the magnitude of the various risks, but the plaintiffs' arguments on this point go to the weight of Dr. Seyler's testimony, not its admissibility. *See In re Lipitor*, 892 F.3d at 631 (trial court's role as gatekeeper not intended to serve as replacement for the adversary system); *cf. Daubert* Ruling at *16 (acknowledgement of conflict in literature goes to weight rather than admissibility).

C. Medical Causation

Finally, Ms. Redick argues that Dr. Seyler's opinions about medical causation are unreliable and are likely to confuse a jury. In particular, she contends that Dr. Seyler's opinion that Ms. Redick may have sustained a femoral neck stress fracture and his statements about Ms. Redick's smoking are so contrary to the evidence as to be unreliable. Smith & Nephew counters that each assertion is supported by the record, is based in Dr. Seyler's differential diagnosis, and is relevant to the issue of medical causation.

Specifically, in a very brief section of his report titled "My opinions of Medical Case/relevant Events," Dr. Seyler opines that Ms. Redick's CT scan and bone scan findings demonstrate "she may have sustained a femoral neck stress fracture" which would have been "consistent with her acute onset sudden hip pain in December," and that "her femoral component had shifted, which is consistent with loosening." (ECF 2512-7, Seyler Report at 13). For those reasons, the report states, Dr. Seyler "[could not] state that the failure of Mrs. Redick's hip resurfacing was caused by a malfunctioning implant." (*Id.*). Additionally, Dr. Seyler notes that Ms. Redick "was an active smoker until 2015[,]" smoking between a quarter and a half a pack of

cigarettes a day. (*Id.* at 10). He states that it is well known that "[c]igarrete smoking decreases bone density and increases the risk of sustaining a fracture and impairs bone healing." (*Id.*). However, Dr. Seyler does not state that smoking or a fracture actually caused Ms. Redick's hip implant to fail. Rather, in a separate section opining on Dr. Shapiro's report, he concludes that "[b]ased on the imaging and Dr. Bowling's revision report, . . . the BHR implant loosened, resulting in pain and the need for revision surgery." (*Id.* at 16). And, in his section offering his "Final Conclusions," Dr. Seyler states that Ms. Redick "began having pain in 2015 and X-rays showed loosening and migration of the BHR device[,]" which he opines was "not due to any defect in the device, but rather was due to failure of Mrs. Redick's underlying bone." (*Id.*).

When questioned about this conclusion during his deposition, Dr. Seyler stated that he did not "think you can say she had a failure of her hip resurfacing" because "there is a lot going on in this case." (ECF 2512-6, Seyler Dep. at 102). He states that there are "multiple reasons why patients can have pain after hip resurfacing," (*id.* at 102), including irritation of the iliopsoas tendons caused by the bigger ball used in resurfacing as compared to total hip replacement, loosening of the implant, the possibility of a hairline fracture, or elevated metal ion levels:

> [R]esurfacing is a much bigger ball than a total hip replacement. So you can get irritation of your ilipsoas tendons that cause pain. If you look at how she describes the pain, that certainly has to be in your list of differential diagnoses, right. She has . . . some radiolucency, which makes you worry is this implant loose or not. . . . Then you have . . . two bone scans. And if you look at the bone scans, there is a clear shift and uptake between the two. In the second one, it's closer to the base of the femoral neck; where if you look at the CT scan, it looks like there may be a hairline fracture. It's very hard to say. It's not the most accurate way to diagnose this, but certainly has to be in there as well. And then you have metal ions as an objective finding, right. . . .

(*Id.* at 103). Dr. Seyler therefore believed that with "all of this combined," there was "enough evidence to do revision surgery." (*Id.*). But he cautioned that he did not think one could say "the revision surgery is caused by a malfunctioned implant" because "there [are] so many other things

that could go on that you cannot say that with certainty." (*Id.* at 103–04).

In sum, Dr. Seyler's opinion contains no original differential diagnosis. *See Westberry*, 178 F.3d at 262 (differential diagnosis typically entails determining possible causes of patient's symptoms and then eliminating each potential cause until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely). He has neither stated which, if any, of the potential alternative causes he identifies likely necessitated Ms. Redick's revision, nor has he ruled out any of those causes. Rather, his opinion is an assertion about what potential causes must be included in Ms. Redick's differential diagnosis.

Ms. Redick contends that Dr. Seyler lacks a factual basis to conclude that she may have had a stress fracture because he admits that her treating physicians never diagnosed such a fracture and he concedes it is ultimately hard to say whether or not she indeed suffered a fracture. (ECF 2512-1 at 9). But Dr. Seyler bases his opinion on the bone scans in Ms. Redick's medical charts; that the scans are not the best means of diagnosing such a fracture and that Ms. Redick's treating physician did not make a diagnosis of fracture are fertile grounds for cross-examination, but not a basis for exclusion. *See In re Lipitor*, 892 F.3d at 631; *see also Westberry*, 178 F.3d at 265–66. And as for Dr. Seyler's mentioning of Ms. Redick's history of smoking, that fact is a part of the medical record. But Dr. Seyler himself fails to mention smoking at all in his lengthy discussion of the factors that must be included in a differential diagnosis. Accordingly, any attempt to introduce this fact at trial may be subject to a challenge under Rule 402 or Rule 403.

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In sum, the court will deny the motion to exclude Dr. Seyler's testimony.

III. Dr. Hungerford

Ms. Mosca seeks to exclude certain portions of Dr. Marc Hungerford's testimony. In

particular, she argues that his opinion about her chromium supplements is not offered to a reasonable degree of certainty as his report and deposition are at odds on the issue; that no sound methodology was used to reach his conclusion about what Dr. Boucher would have done with additional disclosures and about whether Dr. Boucher should have known of the risks posed by the BHR; and that his opinion minimizing the significance of the Australian registry data could be reached only by ignoring sworn testimony to the contrary. The court will address each in turn.

A. Contradictions in Dr. Hungerford's Report and Deposition

Ms. Mosca contends that Dr. Hungerford may not testify about the causal link between Ms. Mosca's use of chromium supplements and her revision surgery given some alleged contradictions in his report and his deposition. (ECF 2511-1 at 5). Dr. Hungerford's report states that Ms. Mosca was taking "a chromium polynicotinate dietary supplement after her BHR implant in 2010" which "may have contributed to elevated chromium levels." (ECF 2511-3, Hungerford Report at 3). During his deposition, Dr. Hungerford stated that he did not believe that the dietary supplement was a cause of the failure of Ms. Mosca's BHR. (ECF 2511-4, Hungerford Dep. at 239). As a result, Dr. Hungerford may not offer the opinion that the chromium supplements necessitated Ms. Redick's revision surgery. *See Huskey*, 29 F. Supp. 3d at 729 (noting that medical causation testimony which is not offered to a reasonable degree of medical certainty amounts to unreliable speculation and is unhelpful to a jury). Notably, though, Smith & Nephew contends that Dr. Hungerford's opinion was not intended to suggest that the chromium supplements *caused* Ms. Mosca's BHR to fail; rather, the opinion is that the supplements may have contributed to Ms. Mosca's metallosis. If offered for this purpose, Dr. Hungerford's contention may be relevant to countering Dr. Shapiro's opinion that Ms. Mosca's BHR led to elevated chromium levels and "necessitated her revision surgery." (ECF 2589-4, Shapiro Report at 7).

B. Improper Methods

Next, Ms. Mosca argues that several of Dr. Hungerford's opinions are based on ipse dixit and are not the product of any reliable methodology.

First, Ms. Mosca challenges Dr. Hungerford's opinion that "there is no indication that any additional information relating to the[] already well-disclosed risks would have changed the decision to use the BHR in Ms. Mosca's surgery." (ECF 2511-3, Hungerford Report at 6). She contends this assertion is unsupported, contradicts Dr. Hungerford's admission that Dr. Boucher would have communicated additional risks to Ms. Mosca, (*see* ECF 2511-4, Hungerford Dep. at 221), and contradicts his concession that there may have been a different outcome if Dr. Boucher was aware the risk was 15 percent, (*see id.* at 166–67). The court has excluded as unreliable Dr. Shapiro's opinion that Ms. Mosca would have received a different implant had different information been provided to Dr. Boucher by Smith & Nephew. *See supra*, Section I.B. Dr. Hungerford's opinion about clinical decisions which Dr. Boucher may or may not have made in light of different information is similarly inadmissible. Though Dr. Hungerford, unlike Dr. Shapiro, does not seek to parrot the implanting physician's deposition testimony, he nevertheless fails to explain why he believes there is "no indication" that additional disclosures would have changed the clinical decision. That Ms. Mosca desired a more active lifestyle and that the BHR at the time was "generally known to have the best track record of any resurfacing implant," (ECF 2511-3, Hungerford Report at 6), cannot be determinative of that decision if, as Dr. Hungerford concedes, the disclosure of certain risks which were *not* generally known may have led to a different outcome, (*see* ECF 2511-4, Hungerford Dep. at 166–67). The court agrees with Ms. Mosca that the testimony of a medical expert concerning actions an implanting surgeon may have taken and which ignores the testimony of that implanting surgeon does not satisfy *Daubert*.

Next, Ms. Mosca challenges Dr. Hungerford's opinion that "[o]rthopedic surgeons such as myself and Dr. Boucher do not rely solely on an implant manufacturer for information, but also engage in ongoing education via journals . . . and many other sources of continuing education." (ECF 2511-3, Hungerford Report at 6). She argues there is a disconnect between this statement and Dr. Hungerford's deposition testimony that her treatment was within the standard of care and she argues that Dr. Hungerford's opinions are based on impermissible conjecture and speculation. Therefore, she contends, Dr. Hungerford's testimony that "Dr. Boucher should have known the magnitude of the revision risk" as reflected in the Australian registry data should be excluded. (ECF 2511-1 at 9). Yet it is difficult to conclude that Dr. Hungerford was actually suggesting Dr. Boucher's conduct fell below the standard of care, or even that Dr. Boucher himself should have known the magnitude of the revision risk. Dr. Hungerford only stated that physicians generally have a professional duty to keep abreast of new information as they attend conferences and lectures and read new studies; not that Dr. Boucher failed to do so. (*See* ECF 2511-4, Hungerford Dep. 167–69). It is unclear how this testimony may be relevant, but the court declines to exclude the testimony as unreliable.[10] [11]

[10] Ms. Mosca's reliance on *Higgins v. Diversey Corp.*, 998 F. Supp. 598 (D. Md. 1997) is unavailing. In that case, the court excluded testimony from an expert who "failed to provide any scientific evidence" linking the relevant injuries to the defendant's product. *Id.* at 602. In this case, Dr. Hungerford is testifying on the basis of his personal experience and upon review of a lengthy list of materials attached to his report at Exhibit 2.

[11] Ms. Mosca also raises a challenge to Dr. Hungerford's statement during his deposition that the ad hoc and published registry data are basically the same thing because the BHR makes up such a large proportion of the market that anything that can be said of the total can be said of the BHR. Her argument is that Dr. Hungerford is not a statistician. This may be true, as far as it goes, though physicians may be qualified to opine on non-medical matters so long as they have sufficient experience, and academic physicians often have significant experience in statistics. The parties have not briefed Dr. Hungerford's credentials well enough to permit the court to rule on this issue at this time, nor is it clear that this issue will be presented at trial.

C. Marketing

Finally, Ms. Mosca wishes to exclude any testimony by Dr. Hungerford which touches on whether Smith & Nephew's use of the Australian registry data in unapproved communications was untruthful or misleading. Ms. Mosca admits that Dr. Hungerford "has not offered any opinions that the marketing was not misleading and was truthful," but wishes to prevent him from offering "contrary testimony at trial." (ECF 2511-1 at 13). This is because Dr. Hungerford has minimized the importance of the Australian registry data. (*See, e.g.*, ECF 2511-3, Hungerford Report at 5 ("Ad hoc data can be unreliable and needs proper analysis before it can serve as the basis for clinical decisions . . . .")). As Smith & Nephew points out, "no data are perfect" and "recognizing this does not mean that Dr. Hungerford believes the [registry data] are always unreliable[.]" (ECF 2589, Opp'n at 10–11). The court agrees and will decline at this time to exclude hypothetical testimony which has not yet been offered.

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In sum, the court will exclude any testimony offered by Dr. Hungerford which posits that Ms. Mosca's chromium supplements necessitated her revision surgery or which opines on hypothetical actions Ms. Mosca's surgeon may have taken in light of additional disclosures. The balance of Dr. Hungerford's opinions will not be excluded at this time.

CONCLUSION

For the reasons described herein, the court will grant in part, reserve in part, and deny in part the motion to exclude the testimony of Dr. Shapiro, deny the motion to exclude the testimony of Dr. Seyler, and grant in part and deny in part the motion to exclude the testimony of Dr. Hungerford. A separate Order follows.

5/17/2021
Date

/s/
Catherine C. Blake
United States District Judge